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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,960

07/08/2005

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06/19/2009

EXAMINER

PATEL, PRITESH ASHOK

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

06/19/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,960	Applicant(s) FUKAI ET AL.	
	Examiner PRITESH PATEL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-9 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-9 and 11-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/16/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 5, and 7-9 are rejected under 35 U.S.C. 102 (e) as being anticipated by Hishikawa (US 6808161 B1).

Concerning claim 1, Hishikawa discloses a sealing valve for a medical apparatus made of an elastic material and having a valve hole at a center which is opened without penetration by a male connection port of said medical apparatus (Fig 1, 3, 4, 5, and 6, elements 32, 33, 34, and 4). Hishikawa also discloses a semispherical portion (near 33) of a sealing valve having a hole in a center of said sealing valve, where a male connection port of a medical apparatus may engage an underside of a semispherical portion thereby pressing and deforming a semispherical portion to open a valve without a male connection port penetrating said valve (Fig 8a).

Concerning claim 5, Hishikawa discloses a cylindrical shaped sealing valve with an arched convex face (Fig 8a and element 3 and 31b).

Concerning claim 7, Hishikawa discloses a connection port (2), a sealing valve as discussed above, a sleeve portion (21) pressing the sealing valve to create a hermetically sealed junction, a screw piece (218) on upper portion of said sleeve in which a syringe can lock in (Fig 12).

Concerning claim 8, Hishikawa discloses an upper end of a sealing valve (3) that is substantially coincident with a sleeve portion (21) and a cushion portion (lower part of

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element 3) that depresses when a male connection port is inserted into said sleeve portion; the depression stops at a predetermined position (Fig 12).

Concerning claim 9, Hishikawa discloses a sleeve portion that serves as a cap to a sealing valve and on said sleeve portion are vertical ridges and valleys (218) that can lock a syringe and said cap together without rotation them against one another (Fig 12).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hishikawa.

Concerning claim 6, Hishikawa discloses a sealing valve with a raised surface portion (Fig 1 and element 30). It would have been obvious to one of ordinary skill in art at the time of the invention to see that the raised portion is an interface for the male connection part of a medical apparatus and it would be obvious to define the area further and create a ring portion.

3. Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hishikawa in view of Schneider (US 5836967).

Concerning claims 11 and 12, Hishikawa discloses a sealing valve, a connection port, a cap member having a sleeve portion, protruding stria on said sleeve portion, a resistance application portion where a locking syringe ceases to couple further, and upon which further insertion deforms said sealing valve, all as disclosed above.

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Hishikawa further discloses a mixed injection tube having multiple connection ports (Fig 19). It would have been obvious to one of ordinary skill that as the screw portion on the upper end of the cap member stops a syringe cannot go further if it has a counter-part to the screw portion and that a double threaded portion would also stop further screwing in of a locking syringe. It would have been further obvious to one of ordinary skill in the art at the time of the invention that the screw portions on the sleeve portion could be male or female and said medical apparatus, specifically a syringe, may have a counter-part to fit said screw portion accordingly. Hishikawa fails to disclose connection ports at both ends of an infusion tube. Schneider discloses many connection ports connecting to an infusion tube (Fig 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hishikawa with multiple connection ports along an infusion tube as taught by Schneider to have multiple points of connection for any medical apparatus needed.

Concerning claims 13, 14, and 15, in addition to the above disclosure, Schneider discloses multiple infusion lumens (Fig 1). It would have been obvious to one of ordinary skill to modify Hishikawa with a multiple lumen catheter as taught by Schneider to be able to implement a connection port as disclosed above in each branch connection tube (elements 23, 24, 12, and 13 of Schneider Fig 1). It would further have been obvious that each branch connection tube can connect with a syringe and that each branch connection tube can lead to any lumen in said catheter.

Response to Arguments

4. Applicant's arguments with respect to claims 1, 5-9, and 11-15 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PRITESH PATEL whose telephone number is (571)270-7025. The examiner can normally be reached on Monday-Friday 7:30Am-5:00PM, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571)272-4977. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. P./

Examiner, Art Unit 3763
06/18/2009

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763